

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

MDL No. 2327

WAVE 1 CASES ON ATTACHED EXHIBIT A

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO
EXCLUDE THE OPINIONS AND TESTIMONY OF MARIA ABADI, M.D.**

Pursuant to Federal Rules of Evidence 702, 403, and 104 Plaintiffs submit this Memorandum of Law in Support of Their Motion to Exclude the General Opinions and Testimony of Maria Abadi, M.D.

I. Dr. Abadi's Experience in Reviewing Prolene Mesh is Limited Solely to this Litigation and Solely to the few Samples Ethicon Counsel Provided Her

Dr. Abadi is a pathologist that had minimal experience reviewing tissue samples from women implanted with any type polypropylene mesh prior to this litigation. Moreover, prior to this litigation it is unlikely that Dr. Abadi had any experience reviewing tissue samples from women implanted with the Prolene Soft mesh, the specific mesh at issue here. After being hired by the Defendant, Dr. Abadi reviewed explanted tissue samples from five Prolene Soft mesh patients. Based on that limited pathology dataset—which was selected by the Defendant— Dr. Abadi wishes to offer a wide variety of general opinions specific to Prolene Soft mesh, including opinions on tissue response following Prolene Soft mesh implantation, Prolene Soft mesh properties, and criticisms of Plaintiffs' expert opinions. Dr. Abadi is unqualified to offer these opinions that are both unreliable and irrelevant and should be excluded by the Court.

II. The Daubert Standard Requires Some Reliable Basis for an Opinion

The proponent of expert testimony must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed.R.Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993).

An expert’s opinion and methodology must be reliable and the expert must reliably apply the methodology to the facts of the case. *Id.* at 592-93. Expert witnesses must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

“The Supreme Court listed several non-exclusive factors to guide courts in their screening function: whether the proposed evidence or theory ‘can be (and has been) tested’; whether it ‘has been subjected to peer review and publication’; whether it has been evaluated in the light of ‘potential rate[s] of error’; and whether the theory has been accepted in the ‘relevant scientific community.’ *Daubert*, 509 U.S. at 593–94.

Even if the expert is qualified and the testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, the testimony must “fit” the case, *i.e.* there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

III. Dr. Abadi's General Opinions Regarding Polypropylene Mesh are Unreliable and Irrelevant

A. Dr. Abadi is Unqualified to Offer General Opinions Regarding Prolene Soft Mesh, Related Tissue Response, or its Medical Sequelae.

Prior to this litigation, Dr. Abadi had never published articles, conducted studies, or performed research on female tissue response to mesh implantation. Exhibit B at 24:22-25:7; 31:12-32:24 (Deposition of Maria Abadi, M.D.). The first time that Dr. Abadi ever wrote about the subject of female tissue response to polypropylene mesh implantation was in her expert report for Defendant. Exhibit B at 24:17-21; Exhibit C (Expert Report of Maria Abadi, M.D.). In fact, Dr. Abadi's only experience with mesh prior to this litigation consisted of reviewing 2 or 3 pathology samples of unknown mesh explants over the past decade:

Q. Your personal experience with interpreting pathological samples that come to you from a surgeon excising mesh, as you, I think, have just said, is a couple of years. Is that accurate?

A. That is correct.

Q. Are we talking two or three a year?

A. Yes, about that.

Q. Would that be true for the last dozen years?

A. Yes, it would be true back for the last decade.

Q. For the last decade, you would see approximately two or three excised mesh samples on an annual basis?

A. Yes.

Q. That's your personal experience world?

A. Yes, outside the litigation part.

Exhibit B at 28:3-28:22.

In addition to her lack of experience with explanted mesh in general, Dr. Abadi has no knowledge of any experience with Ethicon's mesh in particular. It is unknown—and unlikely—

that any of these 20-30 pathology samples came from patients implants with Prolene Soft mesh, the specific mesh at issue here:

Q. When you look at pathology as a cut of tissue under a microscope, you don't know if that sample involves Ethicon's Prolene mesh, AMS's mesh, Boston Scientific mesh, correct?

A. Correct.

....

Q. It is impossible for you to tell us what your personal experience is with pathological review of excised Prolene Soft Mesh?

A. Correct.

Q. You would have no idea what that number is, fair?

A. That is correct.

Q. It would be some fraction of a handful a year for the past decade, fair?

A. Yes.

Q. So if we did two or three a year for ten years, 20 to 30, the number of those that might be Prolene Soft, you couldn't tell us, true?

A. Yes, true.

Q. And if there was a number of any of those that are Prolene Soft, you would have no idea what it is, correct?

A. Yes.

Q. But it would be a fraction, it would be some portion of 20 to 30 at best, correct?

A. Yes, that is correct.

Id. at 29:11-30:22. Therefore, the totality of Dr. Abadi's applicable experience as a pathologist looking at mesh in a non-judicial context prior to this litigation consisted of 20-30 tissue samples that may or may not have included samples with Prolene Soft mesh. Further, she never wrote, published, studied or performed research on tissue response as a general pathological proposition, nor on tissue response to foreign bodies, nor on tissue response to implanted mesh material. Exhibit D (CV of Maria Abadi, M.D.).

Dr. Abadi has no “knowledge, skill, experience, training, or education” pertaining to mesh and related tissue response that could qualify her to render opinions in these cases. Fed.R.Evid. 702.¹ At the very least, this litigation should require that a pathologist have some experience beyond that of a hospital based anatomic pathologist. Dr. Abadi’s only specialized experience beyond that is in the HPV virus and PAP smears, which certainly is not a relevant knowledge base to qualify her to offer opinions here. Therefore, Dr. Abadi is unqualified to offer any general opinions about Prolene Soft mesh and related tissue response, and they should be struck *in toto*.

B. The Basis of Dr. Abadi’s General Opinion Regarding Tissue Response to Prolene Mesh is Limited to 5 Explant Samples She Received from Ethicon Counsel in this Litigation.

Even if Dr. Abadi is found to be qualified to offer opinions regarding polypropylene mesh and related tissue response, her general opinions regarding host tissue response to Prolene Soft mesh and the absence of any clinical effect as a result are unreliable and irrelevant. These are litigation opinions, with a limited sample size of unknown origin or basis, and with no scientific basis (nor even experience) as a foundation. Dr. Abadi conceded this limited foundational basis in her own testimony. Time and again, Dr. Abadi admitted in her deposition that her opinions are based entirely on her review of five (5) tissue samples that were provided to her by the Defendant:

Q. Are your opinions that are laid out in your report opinions based on the host tissue response to polypropylene mesh in general?

A. Well, the tissue samples that I reviewed were from cases that used Prolene Soft Mesh, and therefore, my opinions are based on that.

¹ Circumstances help explain how someone like Dr. Abadi, who practices as a general anatomic pathologist in a hospital setting and admittedly does not address mesh explants on anything more than a tangential basis, gets hired. Another pathology expert for Ethicon, with a more specialized practice in gynecologic pathology, is Dr. Abadi’s former director and referred Ethicon’s counsel to her to serve as an additional expert on their behalf in the Wave 1 cases. Exhibit B at 54;20-56:11.

Q. So the opinions that you have regarding the host tissue response are based upon your personal review of five cases of explanted materials of women who were implanted with Prolene Soft Mesh?

A. Yes.

Q. And that was the samples that were provided to you and you have personally reviewed that you knew the pathology was related or was sourced by Prolene Soft?

A. Yes.

....

Q. So the basis for your opinions regarding the host tissue response to Ethicon mesh is based on your personal review of five explanted materials that were specifically Prolene Soft Mesh.

A. Yes.

Id. at 75:15-77:3;

Q. So you told us that you have opinions that are based upon review of five specific cases in this matter, correct?

A. Right, correct.

Id. at 119:5-8;

Q. So when we have talked today about the basis for your opinions in this matter, again, the pathological samples of explanted mesh that form the basis for your opinions were the five that were sent to you by Ethicon, correct?

A. Yes.

Id. at 155:15-21.

Dr. Abadi's examination of five tissue samples is certainly not a reliable basis for her to offer incredibly broad, general opinions about female tissue response to Prolene Soft mesh and its proper use in female pelvic surgery. Further, Dr. Abadi provides no explanation in her report or deposition as to how the five tissue samples she reviewed were selected or prepared for examination. This Court has excluded pathology expert opinions based on unknown and

unexplained pathology sample selections, particularly when those opinions are general rather than patient specific. Without an in-depth understanding of the sample selection process there is no way to assess bias, error rate, or if a representative sample was provided to the expert. *See Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 673-74, 711 (S.D.W. Va. 2014); *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *8 (S.D.W. Va. Jan. 15, 2014), *reconsideration denied sub nom. In re Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014); *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 555 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014). The same logic applies here.

C. Dr. Abadi's Opinions About Prolene Mesh, Tissue Reaction, and the (absence of) Medical Sequelae are Unreliable

Dr. Abadi's report narrates several general principles of wound healing. At Page 7, she transitions to her opinions about Prolene Soft mesh and its effects inside the body. It is at this point that Dr. Abadi lacks any foundation or qualifications to opine on all matters that follow.

For example, she opines:

Masson trichrome-stained sections reveal that the deposition of mature collagen is evident around the fibers and blends seamlessly with the surrounding stroma. There is no evidence of encapsulation or hypertrophic, nodular scar formation such as the one seen in porcine collagen coated meshes, porcine dermis or cadaveric grafts. Furthermore, the macroporous knitted design facilitates cellular adherence and vessel ingrowth into the mesh. Vessel ingrowth is an important factor in the maintenance of nutrient delivery to the tissues.

Exhibit C at p.7. The "masson trichrome-stained sections" to which she refers are the five previously discusses explanted mesh samples provided to her by the Defendant. The lack of "evidence" of encapsulation of scar formation to is based on a review of the five explanted mesh samples provided to her by Defendant. The design [of Prolene Soft Mesh] and its facilitation of any tissue response is, again, based on the five explanted mesh samples provided to her by Defendant. These opinions should be excluded.

Dr. Abadi then transitions, at Page 9, to a laundry list of “opinions” responding to Plaintiffs’ pathology expert. These are all general causation opinions framed as rebuttal. An unqualified expert does not get to offer unreliable opinions simply because she qualifies them as “rebuttal” of another expert. In each element, Dr. Abadi attempts to opine about Prolene Soft mesh and its causative association to:

1. Pain and Nerve Damage
2. Mesh Stiffening, Contraction, and Shrinkage
3. Deformation and Mesh Migration
4. Polypropylene Degradation
5. Degenerative Calcifications
6. Mucosal erosion and tissue edema

Id. at 9. These opinions are again based on her review of five explanted mesh samples provided her by Defendant, and a review of Plaintiff’s Expert Report.² Dr. Abadi should not be allowed to give unreliable and unqualified opinions on Prolene Soft mesh and its relation to these six areas of clinical sequelae, whether affirmatively or in rebuttal.

Finally, Dr. Abadi’s “Summary” encapsulates the failure of her basis or method to be able to offer a reliable opinion. She concludes “The histological findings in these cases are multifactorial...”. Exhibit C at p.13. Again, that general conclusion is based on a limited sample size of five with no reliable source. From this summary, she again improperly and unreliably tries to opine about general female response to implanted Prolene Soft mesh and that “most cases” show “focal and stable foreign body reaction” and do “not show encapsulation.” “Most cases” meaning five cases. She simply has no reliable basis for such general opinion, affirmatively or in rebuttal,

² In contrast to Dr. Abadi’s opinions, Plaintiffs’ expert, Dr. Vladimir Iakovlev, bases his opinions on a personal review of over 250 mesh explants, his own peer reviewed publications on the topic, and a comprehensive literature review with articles cited for each proposition – which Dr. Abadi attempts to rebut.

and a jury will not be assisted by Dr. Abadi's "rebuttal" about another expert on matters in which she has no experience or basis to offer such opinion.

Conclusion

For these reasons, Dr. Abadi's is unqualified to offer the general opinions set out in pages 7-13 of her report regarding (1) "Prolene Soft Mesh Properties" and related tissue response; (2) her list of six areas of medical sequelae; (3) comments about the reliability of Dr. Iakolev's opinions; (4) the general opinions in her "Summary" on Prolene Soft mesh; (5) her "observed tissue response" attributed to Prolene mesh (in five cases); (6) the clinical effect of such; and (7) the comment about Dr. Iakolev's opinions. Further, these opinions are unreliable and should be struck.

DATED: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 21, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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